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(54) **Device for mouth-inhaling aerosol medicaments.**

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FR-A- 1 602 651
FR-A- 2 352 556
GB-A- 1 118 341

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Description

This invention relates to a device for mouth-inhaling atomized medicaments dispensed by an aerosol can.

Inhalation is the preferred system for administering medicaments (such as beta-adrenergic, antiallergic and anti-inflammatory drugs) directed to the deeper parts of the respiratory tree in that it considerably reduces the dose compared with oral administration. It almost completely eliminates systemic side-effects and provides rapid onset of therapeutic action.

For this purpose pressurized cans containing the medicament and a propellant are used, the cans being provided with dispensers which when manually operated dispense metered doses of atomized medicament through a nozzle.

Because of their portability and because they allow rapid and selective administration of the active principle, these cans have encountered considerable favour and are widely used both in maintenance therapy of chronic obstructive respiratory diseases and in the treatment of acute asthmatic attacks.

Notwithstanding their apparent simplicity, common pressurized cans for dispensing metered doses of aerosol are difficult to use correctly, as is confirmed by much scientific literature which states that most patients use them incorrectly either because they are unable to synchronize pressing the can with inhaling and hence do not inhale the medicament at the correct time or because the patient does not maintain an adequate inspiratory flow rate or does not inhale deep enough, among other reasons.

This problem becomes even more important in the case of certain patients such as children, the elderly and patients with reduced respiratory or manual capability.

Even if a dispensing can for erosol medicaments is used correctly, the availability of an inhaled medicament to the air ways depends largely on the size of the aerosol droplets (propellant droplets enclosing medicament particles), which is governed by the formulation, and on the propellant evaporation time.

It is any event well documented that even under the most favourable conditions only 10% of the aerosol dose discharged by a pressurized can reaches the air ways. A similar percentage is expired or is deposited outside the oral cavity, whereas because of the impact of the high speed particles about 80% is deposited within the oropharyngeal cavity, swallowed systemically adsorbed and hence practically lost.

The quantity of medicament inhaled is however usually sufficient to achieve the pharmacological effect.

However, if the pressurized can is not used properly the quantity of medicament which reaches the site of action at the pulmonary level is further reduced and the therapeutic response is compromised.

Excessive aerosol depositing in the oropharyngeal cavity can also lead to undesirable effects either at systemic level as a consequence of the drug absorption, or at the local level, as in the case of corticosteroids, which can result in oral candidiasis. In an attempt to overcome the problems connected with the use of cans releasing metered doses of aerosol medicament, auxiliary delivery systems have been developed over the last decade for application to the nozzles of pressurized dispensing cans. Depending on their size these devices can be classified as either "spacers" or "reservoirs".

In practice, "spacers" are tubes to be interposed between the can dispensing nozzles and the mouth of the user to improve the delivery of the aerosol to the lungs by decreasing the size and velocity of the aerosol droplets so reducing their impact within the oropharyngeal cavity.

In this respect, the delay between the generation of the aeorosol and its inhalation allows rapid evaporation of the propellant and a resultant decrease in the size of the particles before they enter the respiratory tree, so favouring improved penetration as far as the lower air ways.

Again the distance which the "spacers" device interposes between the dispensing nozzle and the patient's mouth facilitates the evaporation of the propellant vapour and decreases the particle speed, so reducing the percentage of medicament lost due to immediate impact with the oral cavity.

Finally, the quantity of inhaled propellant is reduced, with consequent greater pleasantness for the user and a lessening of possible harmful effects of the solvents.

The "spacer" devices of the aforesaid type have the common characteristic of a substantially cylindrical shape and a fairly small volume (70-100 ml).

The use of this type of "spacer" device has rapidly become extensive as an aid to those patients who are unable to properly use the common cans for dispensing metered doses of aerosol or who have difficulty in understanding the rather complicated instructions.

Evidence from scientific literature shows however that the addition of small "spacers" does not produce appreciable improvement of the therapeutic response.

For this reason reasearch in this sector has been directed to the design of devices in the form of actual large volume reservoirs or holding chambers.

Besides possessing the advantages attributed to the "spacers" these "reservoirs" should contribute to resolving the considerable problem of lack of coordination between actuating the aerosol and inhaling because they enable intake to be delayed after delivery, hence aiding patients with more serious respiratory difficulties.

However, known "reservoirs" have considerable

drawbacks which hinder their use and acceptability. In this respect, as the aerosol jet is sprayed into the chambers cavity the aerosol droplets strike the chamber walls to then diffuse into the central region of the chambers. A large number of the medicament droplets tend to deposit on the chamber walls and are lost. To reduce this problem, the known "reservoirs" are of a large size (for example about 750 ml), making their portable use practically impossible and creating storage problems for the factory and pharmacy. A device of this type is described in GB patent 1,565,029.

A further example of prior art devices is disclosed in FR-A-1 602 651.

The main object of this invention is to provide a mouth-inhaling device for use with pressurized cans for dispensing metered doses of medicament, the inhaler device being of low cost, small overall size to facilitate factory and pharmacy storage and to enable it to be contained in a handbag or jacket pocket, portable, easy to use, and very simple to fit to a pressurized can. Said device is designed to favour the inhaling of a greater number of active particles and to avoid spaying the aerosol directly onto the mucosa of the oropharynx in order to safeguard the user against side- effects deriving from direct spray into the mouth. In this respect, the device has an expansion chamber shaped to create, by virtue of the speed at which the aerosolized material is expelled by the dispenser, a vortex flow in which the particles remain in suspension for sufficient time to enable them to discharge their kinetic energy and allow substantial evaporation of the propellant, with a consequent reduction in the size and in the velocity of the particles, leading to a more efficient intrapulmonary delivery, while large size particles are centrifuged onto the walls of the chamber, to deposit on them.

The invention therefore provides a device for mouth-inhaling medicaments, dispensed as aerosols by pressurized cans, comprising a body with a seat for housing a can provided with a stem for operating the can dispensing valve, a chamber for the collection and expansion of the aerosol dispensed by a discharge nozzle on the can, and mouthpiece communicating with said chamber and projecting outwards from said body the chamber being delimited by a curved wall, characterized in that said body has a substantially flat shape, said curved wall delimiting said chamber into a first peripheral portion of which there opens the inner end of said mouthpiece, and in a second peripheral portion of which, opposite the first, there is an aperture from which two walls extend outwards from the chamber to converge towards the can discharge nozzle and define a duct, the central plane of which is inclined to the central plane of said mouthpiece, in such a manner as to generate within said chamber a vortex in the aerosol discharged by the can.

The structure and characterisics of the inhaler device will be more apparent from the description of a prefered embodiment thereof given by way of non-limiting example with reference to the accompanying drawings, in which:

Figure 1 is a perspective view of the inhaler device;

Figure 2 shows one of the two shells forming the device, viewed in the direction indicated by the lines 2-2 of Figure 1; and

Figures 3 and 4 are sections through the inhaler device on the lines 3-3 and 4-4 of Figure 1.

The inhaler device shown in the figures is of a decidedly flat shape. It is formed from two specular shells 1 and 2 which can be joined together by simple pressure by the provision of holed appendices and pegs 12 provided on the inside of the shell 1 and shell 2 respectively (Figure 2).

A curved wall 10 projects inwards from the shell 1 (Figures 1 to 3), whereas a curved wall 20, specular to the wall 10, projects inwards from the shell 2 (Figures 3 and 4). When the two shells 1 and 2 have been joined together, the two walls 10 and 20 define with the two shells and expansion chamber 3, at which the two shells comprise outwardly projecting convex portions for the purpose of increasing the chamber area.

A mouthpiece projects from a first peripheral portion of the walls 10, 20 and is defined by two appendices 4, 5 projecting from the shells 1 and 2 respectively. The two appendices 4, 5 define a passage 6 the inner end of which opens into said chamber.

It can be seen from Figure 2 that in a second peripheral portion of the curved wall 10, 20 opposite that from which the mouthpiece 4, 5 projects there is an aperture from which two walls 11 and 21, respectively (Figure 4) extend outwards from the chamber to converge (Figure 2) towards the exit hole of a shaped nozzle 15 housed and retained in two seats 13 and 14 projecting from the shells 1 and 2 respectively.

The body 1, 2 also defines a seat, external to the expansion chamber, which can receive by axial insertion a can 16 of known type (shown by dashed lines in Figure 2), provided with a hollow stem 17 which is inserted and retained in a seat provided in the shaped nozzle 15. The can is preferably of the pressurized type in order to dispense metered doses of aerosol each time the stem 17 is pushed, and it can be seen that the end of the can distant from the end provided with the stem projects outside the body 1, 2. Finally, it should be noted that the centre plane 30 though the mouthpiece 4, 5 is inclined to the centre plane 40 between the convergent walls 11, 21, these centre planes being shown by dashed and dotted lines in Figure 2.

When the pressurized can 16 has been housed in its housing in the body 1, 2, with the stem 17 inserted into the seat of the shaped nozzle 15, the body 1, 2 can be gripped with one hand, the mouthpiece 4, 5 placed in the mouth and the base of the can 16 press-

ed with one finger, the stem remaining fixed and at rest in the nozzle 15. This results in the opening of the dispensing valve within the can, from which a measured quantity of aerosol emerges through the open end of the hole in the nozzle 15, to pass between the diverging walls 11, 12 and penetrate into the expansion chamber delimited laterally by the curved walls 10, 20, which are shaped to impose on the aerosol jet a vortex motion which results in deposition of the largest particles on the walls 10, 20 whereas the other particles lose their layer of propellant and hence reduce in diameter.

Although the spray dispensed by the can is very violent and of very short duration, the aerosol mass which expands and rotates with vortex motion within the expansion chamber remains in movement for a considerably longer time than the duration of discharge from the can.

Because of its particular constructional characteristics the device of the present invention can perform the double function of sustained delivery metered dose inhaler and spacer, so satisfying the various treatment requirements and adapting to the needs of the patient.

In this respect, the patient can remove the cover and insert the mouthpiece 4, 5 into his mouth at the moment of dispensing, or alternatively he can actuate the dispenser with the device closed and afterwards remove the cover and insert the mothpiece into his mouth.

In either case, the patient can repeatedly inhale the aerosol, the droplets of which are of a very small size and can thus reach deep into the bronchial tree, whereas only a minimum quantity of such droplets deposits on the walls of the oral cavity.

Hence it can be seen that the described inhaler device (provided with a cover 8 for the closure and protection of the mouthpiece 4, 5, on which it is retained by engagement between the projections 9 and the projections 7 shown in Figure 1) is of a very simple and economical structure and of minimum bulk, so that it can be carried in a handbag or in a jacket pocket.

It also gives the aerosol jet emitted by the can a vortex flow within a small dimension expansion chamber, so that the highest number of small-dimension particles, pratically free from propellant, follow the direction of flow of the inhaled air, limiting the undesirable side-effects deriving from direct spraying onto the oropharynx mucosa.

The can is easily fitted and removed and the device can be easily washed. In a further embodiment of the invention the can could be immovably inserted into a seat provided in the device and the aerosol be dispensed by operating a pushbutton or the like which acts directly on the stem or dispenser on the can.

Claims

1. A device for mouth-inhaling medicaments dispensed as aerosols by pressurized cans, comprising a body (1, 2) with a seat for housing a can (16) provided with a stem (17) for operating the can dispensing valve, a chamber (3) for the collection and expansion of the aerosol dispensed by a discharge nozzle (15) on the can (16), and an inhalation mouthpiece (4, 5) communicating with said chamber (3) and projecting outwards from said body (1, 2), the chamber (3) being delimited by a curved wall (10, 20), characterized in that said body (1, 2) is of substantially flat shape, said curved wall (10, 20) delimiting said chamber (3) into a first peripheral portion of which there opens the inner end of said mouthpiece (3, 4), and in a second peripheral portion of which, opposite the first, there is an aperture from which two walls (11, 21) extend outwards from the chamber (3) to converge towards the can discharge nozzle and define a duct the axis of which is inclined to the axis of said mouthpiece, in such a manner as to generate within said chamber (3) a vortex in the aerosol discharged by the can (16).

2. An inhaler device as claimed in claim 1, characterized in that said body (1, 2) is constructed as two shells (1), (2) provided with elements (12) enabling them to be joined together, there being housed and retained in the interior of the body (1, 2) a dispensing element (15) having a seat (18) into which the can stem (17) can be inserted, from said seat (18) there extending a hole which opens in an intermediate position between the ends of said walls which converge outwards from said chamber.

3. An inhaler device as claimed in claims 1 and 2, characterized in that said can housing seat is shaped to allow axial movement of the can (16), of which that end distant from the end provided with the valve projects from said body and can be driven by one finger to move towards the valve stem (17) and hence cause dispensing of the medicament.

Patentansprüche

1. Vorrichtung zum Mundinhalieren von Medikamenten, die als Aerosole durch unter Druck gesetzte Dosen gespendet werden umfassend ein Hauptteil (1, 2) mit einem Sitz zum Unterbringen einer Dose (16), die mit einem Schaft (17) zum Betätigen des Dosenspenderventils versehen ist, eine Kammer (3) für das Sammeln und die Ex-

pansion des mittels einer Entladungsdüse (15) auf der Dose (16) gespendeten Aerosols, und ein Inhalationsmundstück (4, 5), das mit der Kammer (3) in Verbindung steht und von dem Hauptteil (1, 2) auswärts vorsteht, wobei die Kammer (3) durch eine gekrümmte Wand (10, 20) begrenzt ist, dadurch **gekennzeichnet**, daß das Hauptteil (1, 2) von im wesentlichen flacher Form ist die gekrümmte Wand (10, 20) die Kammer (3) in einen ersten Umfangsbereich derselben begrenzt, wo das innere Ende des Mundstücks (3, 4) mündet, und in einen zweiten Umfangsbereich derselben, der entgegengesetzt dem ersten ist, wo eine Öffnung vorhanden ist, von welcher sich zwei Wände (11, 21) nach auswärts von der Kammer (3) erstrekken, um nach der Dosenentladungsdüse hin zu konvergieren und einen Kanal zu begrenzen, dessen Achse zu der Achse des Mundstücks in einer solchen Art und Weise geneigt ist, daß innerhalb der Kammer (3) ein Wirbel in dem mittels der Dose (16) entladenen Aerosol erzeugt wird.

2. Inhalatorvorrichtung nach Anspruch 1, dadurch **gekennzeichnet**, daß das Hauptteil (1, 2) als zwei Schalen (1), (2) aufgebaut ist, die mit Elementen (12) versehen sind, welche es ihnen ermöglichen, miteinander verbunden zu werden, wobei in dem Inneren des Hauptteils (1, 2) ein Spendeelement (15) untergebracht und gehalten ist, das einen Sitz (18) hat, in welchen der Dosenschaft (17) eingefügt werden kann, wobei sich von dem Sitz (18) aus eine Öffnung erstreckt, welche in einer zwischenliegenden Position zwischen den Enden der Wände mündet, die auswärts von der Kammer konvergieren.

3. Inhalatorvorrichtung, wie in den Ansprüchen 1 und 2 beansprucht, dadurch **gekennzeichnet**, daß der die Dose aufnehmende Sitz so geformt ist, daß er eine Axialbewegung der Dose (16) ermöglicht, von welcher jenes Ende, das von dem mit dem Ventil versehenen Ende entfernt ist, aus dem Hauptteil vorsteht und mittels eines Fingers getrieben werden kann, um es nach dem Ventilschaft (17) zu zu bewegen und demgemäß ein Spenden des Medikaments zu bewirken.

Revendications

1. Dispositif d'inhalation par voie buccale de médicaments distribués sous forme d'aérosols par des récipients sous pression, comportant un corps (1, 2) avec un siège pour loger un récipient (16) muni d'une tige (17) d'actionnement de la soupape de distribution du récipient, une chambre (3) de collecte et de dilatation de l'aérosol débité par une buse de distribution (15) disposée sur le récipient (16) et un embout d'inhalation (4, 5) en communication avec ladite chambre (3) et faisant saillie vers l'extérieur depuis ledit corps (1, 2), la chambre étant délimitée par une paroi incurvée (10, 20),
caractérisé en ce que ledit corps (1, 2) est sensiblement plat, la paroi incurvée (10, 20) séparant ladite chambre (3) en une première partie périphérique dans laquelle débouche l'extrémité intérieure de l'embout (4, 5) et une deuxième partie périphérique où est disposé, à l'opposé de la première partie, une ouverture de laquelle s'étendent deux parois (11, 21) vers l'extérieur de la chambre (3) pour converger vers la buse de distribution du récipient et définir un conduit dont l'axe est incliné par rapport à l'axe dudit embout, de manière à engendrer à l'intérieur de ladite chambre (3) un tourbillon d'aérosol débité par le récipient (16).

2. Dispositif d'inhalation selon la revendication 1, caractérisé par le fait que ledit corps (1, 2) est réalisé sous la forme de deux coquilles (1, 2) munies d'éléments (12) pour pouvoir les réunir, un élément distributeur (15) étant logé et maintenu à l'intérieur du corps (1, 2), cet élément présentant un siège (18) dans lequel peut être insérée la tige (17) du récipient, un trou s'étendant à partir dudit siège (18) qui s'ouvre dans une position intermédiaire entre les extrémités desdites parois qui convergent vers l'extérieur de la chambre.

3. Dispositif d'inhalation selon les revendications 1 et 2,
caractérisé en ce que le siège de logement du récipient est réalisé pour permettre un mouvement maximum du récipient (16) dont l'extrémité opposée à celle qui porte la soupape fait saillie du corps et peut être déplacée par un doigt pour déplacer la tige (17) vers la soupape et provoquer ainsi la distribution du médicament.

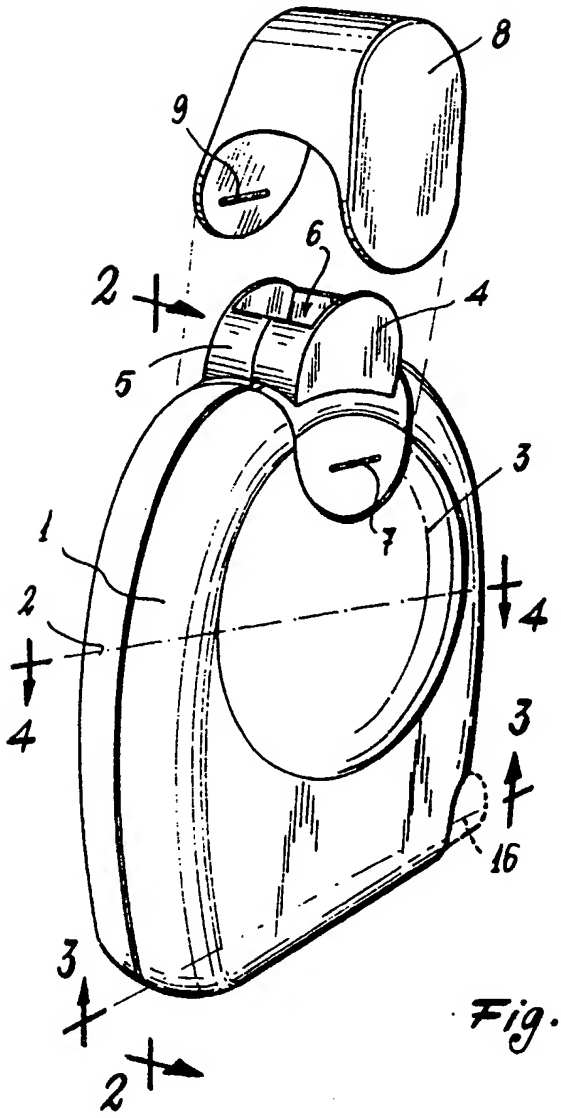

Fig. 1

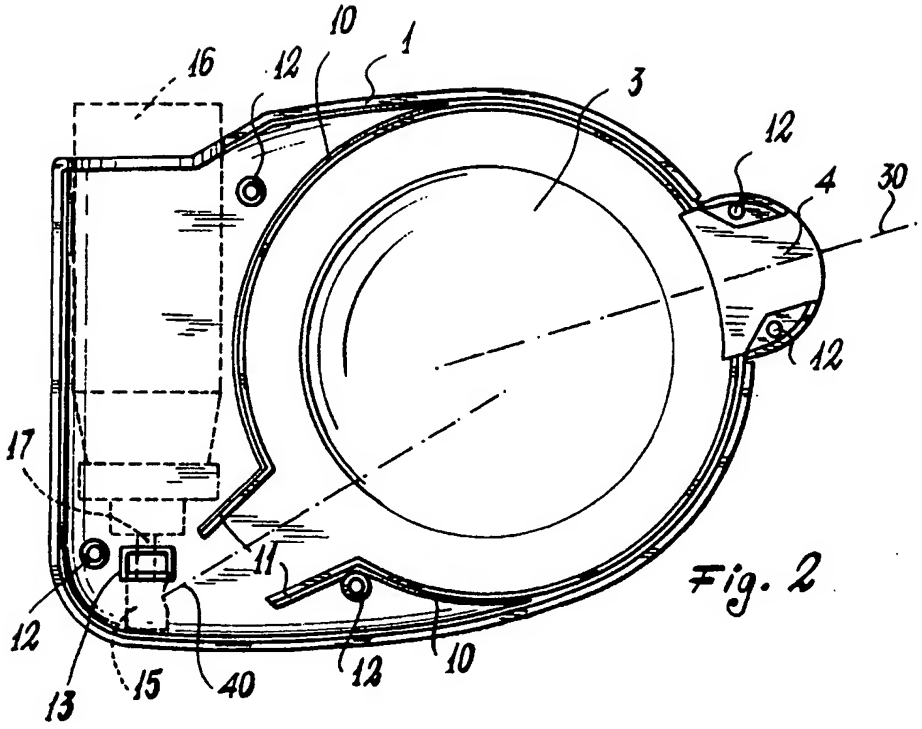

Fig. 2

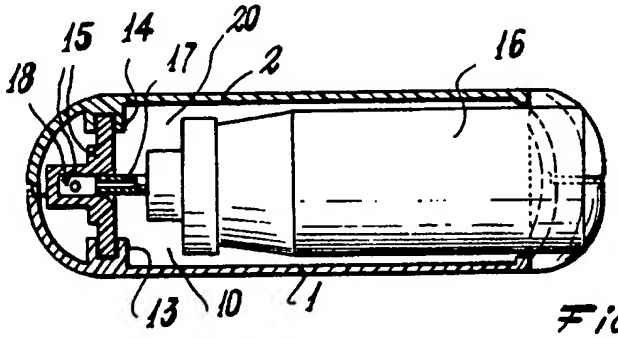

Fig. 3

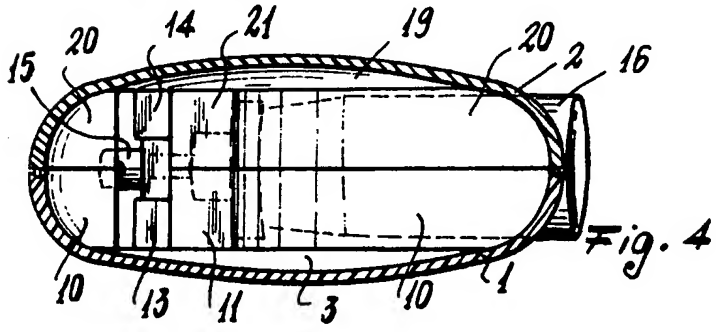

Fig. 4